Page 38, line 33, add - -r- - before "AAV", remove "hFIX" and replace with - -human factor IX- -.

Page 39, lines 6 and 18, delete "recombinant" and introduce - -r- - before "AAV"; and replace "Human" with --human--; and

line 33, replace "Human" with --human--.

IN THE CLAIMS

1. (Amended) A method for providing liver specific expression of a therapeutic gene, said method comprising:

administering recombinant adeno-associated (rAAV) particles to a mammalian cell, said rAAV particles comprising a polynucleotide encoding a therapeutic protein under control of a regulatory region for gene expression in human liver cells, wherein the viral particles provide for liver specific expression of said therapeutic protein following infection of said mammalian cell.

4. (Amended) The method of claim 1, wherein said mammalian cells are infected with rAAV particles ex vivo, then delivered into the portal vasculature of a mammal resulting in liver specific expression of the therapeutic protein.

7. (Amended) The method of claim 1, wherein said rAAV viral particles comprise:

a regulatory region for gene expression in human liver cells,

a structural gene encoding a therapeutic protein selected from the group consisting of factor VIII, factor IX and GM-CSF, and

two AAV inverted terminal repeats, wherein said inverted terminal repeats flank the promoter and structural gene.

15. (Amended) The method of claim 1, wherein said polypeptide is diffusible.

27. (Amended) A method of treating a liver disease or disorder in a mammal, comprising:

administering a therapeutically effective dosage of recombinant adeno-associated (rAAV) particles to the liver cells of said mammal, said rAAV particles comprising a polynucleotide encoding a therapeutic protein selected from the group consisting of factor VIII, factor IX and GM-CSF under control of a regulatory region for gene expression in human liver cells, wherein the viral particles provide for liver specific expression of said therapeutic protein upon infection said liver cells.

31. (Amended) A method of treating a disease or disorder in a mammal, comprising:

administering a therapeutically effective dosage of a recombinant adeno-associated (AAV) vector to the liver cells of said mammal, wherein said recombinant AAV vector comprises a polynucleotide operably linked to a liver-specific promoter or enhancer, wherein said polynucleotide encodes factor VIII, factor IX or GM-CSF.

36. (Amended) A method of gene therapy for a mammal, comprising:

administering a therapeutically effective dosage of a recombinant adeno-associated (AAV) vector to the liver cells of said mammal, wherein said recombinant AAV vector comprises a polynucleotide operably linked to a liver-specific promoter or enhancer, wherein said polynucleotide encodes factor VIII, factor IX or GM-CSF.

43. (Amended) A pharmaceutical composition for treating a liver disorder comprising:

recombinant adeno-associated (AAV) particles comprising a structural gene

encoding a therapeutic protein selected from the group consisting of factor VIII, factor IX, and GM-CSF;

a regulatory region for gene expression in human liver cells; and

a pharmaceutically acceptable carrier.

Please add the following new claims:

--57. The method of claim 7, wherein said regulatory region for gene expression in human liver cells is a tissue-specific promoter active in hepatic cells.

58. The method of claim 1, wherein said regulatory region for gene expression in human liver cells is selected from the group consisting of the albumin promoter, the α fetoprotein promoter, the α fetoprotein enhancer, the human apolipoprotein E (ApoE) promoter, HCR-1, HCR-2, the AI apolipoprotein liver-specific enhancer and the a1-antitrypsin promoter.

59. The method of claim 1, wherein said therapeutic protein is factor VIII and said therapeutic effect is an improvement in the coagulation defect.

60. The method of claim 1, wherein said therapeutic protein is factor IX and said therapeutic effect is an improvement in the coagulation defect.

61. The method of claim 4, wherein said rAAV viral particles comprise:

a regulatory region for gene expression in human liver cells,

a structural gene encoding GM-CSF, and

two AAV inverted terminal repeats, wherein said inverted terminal repeats flank the promoter and structural gene.

62. The method of claim 27, wherein said regulatory region for gene expression in human liver cells is a tissue-specific promoter active in hepatic cells.

63. The method of claim 27, wherein said regulatory region for gene expression in human liver cells is selected from the group consisting of the albumin promoter, the α fetoprotein promoter, the α fetoprotein enhancer, the human apolipoprotein E (ApoE) promoter, HCR-1, HCR-2, the AI apolipoprotein liver-specific enhancer and the a1-antitrypsin promoter.

64. The method of claim 27, wherein said therapeutic protein is factor VIII and said therapeutic effect is an improvement in the coagulation defect.

65. The method of claim 27, wherein said therapeutic protein is factor IX and said therapeutic effect is an improvement in the coagulation defect.

66. The method of claim 27, wherein said administering further comprises:

injecting said recombinant AAV vector into the portal vasculature of said mammal.

67. The pharmaceutical composition of claim 43, wherein said regulatory region for gene expression in human liver cells is a tissue-specific promoter active in hepatic cells.

68. The pharmaceutical composition of claim 43, wherein said regulatory region for gene expression in human liver cells is selected from the group consisting of: the albumin promoter, the α fetoprotein promoter, the α fetoprotein enhancer, the human apolipoprotein